

CLAIMS

1. A pharmaceutical composition comprising (i) a polynucleotide encoding an HIV envelope protein and (ii) a polynucleotide encoding a CD4 receptor.
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2. A pharmaceutical composition comprising (i) a polynucleotide encoding an HIV envelope protein and (ii) a polynucleotide encoding a CD4 receptor wherein (i) and (ii) are encoded on separate vectors.
- 10 3. A pharmaceutical composition comprising (i) a polynucleotide encoding an HIV envelope protein and (ii) a polynucleotide encoding a CD4 receptor wherein (i) and (ii) are encoded on the same vector.
4. A pharmaceutical composition according to any one of the preceding claims
15 wherein said HIV envelope protein and said CD4 receptor are expressed as separate proteins.
5. A pharmaceutical composition comprising (i) a polynucleotide encoding an HIV envelope protein and (ii) a CD4 receptor.
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6. A pharmaceutical composition according to any one of the preceding claims wherein the HIV envelope protein is expressed as part of a fusion protein and/or the CD4 receptor is expressed as part of a fusion protein.
- 25 7. A pharmaceutical composition according to any one of the preceding claims wherein the CD4 receptor is soluble CD4 receptor.
8. A pharmaceutical composition according to any one of the preceding claims wherein the CD4 receptor is human CD4 receptor.
- 30 9. A pharmaceutical composition according to any one of the preceding claims wherein the CD4 receptor is a CD4 surrogate molecule.

10. A pharmaceutical composition according to claim 9 wherein the CD4 surrogate molecule is M33 mini-protein.
- 5 11. A pharmaceutical composition according to any one of the preceding claims wherein the HIV envelope protein is HIV-1 envelope protein.
12. A pharmaceutical composition according to any one of the preceding claims wherein the HIV envelope protein is CCR5-dependent HIV envelope protein.
- 10 13. A pharmaceutical composition according to any one of the preceding claims wherein the polynucleotide encoding the HIV envelope protein encodes gp160.
14. A pharmaceutical composition according to any one of the preceding claims
- 15 further comprising a pharmaceutically acceptable diluent or excipient.
15. A pharmaceutical composition according to any one of the preceding claims for use in the treatment of HIV.
- 20 16. A pharmaceutical composition according to any one of claims 1-15 in the form of a vaccine.
17. A method of treating or preventing HIV infection which method comprises administering to a subject a pharmaceutical composition as defined in any one of
- 25 claims 1-14.
18. A method according to claim 17 wherein the administration of the pharmaceutical composition is in proximity of a superficial lymph-node station.
- 30 19. A delivery system for (i) a polynucleotide encoding an HIV envelope protein and (ii) a polynucleotide encoding a CD4 receptor.

20. A delivery system according to claim 19 wherein said HIV envelope protein and said CD4 receptor are expressed as separate proteins.
21. A delivery system for (i) a polynucleotide encoding an HIV envelope protein and (ii) an sCD4 receptor.
22. A delivery system according to claims 19 or 21 wherein (i) and (ii) are administered simultaneously.
23. A delivery system according to any one of claims 19 to 22 wherein the CD4 receptor is soluble CD4 receptor.
24. A delivery system according to any one of claims 19 to 23 wherein the CD4 receptor is human CD4 receptor.
25. A delivery system according to any one of claims 19 to 24 wherein the CD4 receptor is a CD4 surrogate molecule.
26. A delivery system according to claim 25 wherein CD4 surrogate molecule is M33 mini-protein.
27. A delivery system according to any one of claims 19 to 26 wherein the HIV envelope protein is HIV-1 envelope protein.
28. A delivery system according to any one of claims 19 to 27 wherein the HIV envelope protein is CCR5-dependent HIV envelope protein.
29. A delivery system according to any one of claims 19 to 28 wherein the polynucleotide encoding the HIV envelope protein encodes gp160.

30. A delivery system according to any one of claims 19 to 29 wherein the polynucleotides or polypeptides are administered orally, intracavernosally, intravenously, intramuscularly, subcutaneously, topically or by inhalation.
- 5 31. A fixed cell wherein said cell expresses an HIV envelope protein and further wherein said envelope protein is complexed with a CD4 receptor.
32. A fixed cell according to claim 31 wherein the CD4 receptor is soluble CD4 receptor.
- 10 33. A fixed cell according to claim 31 or 32 wherein the CD4 receptor is human CD4 receptor.
34. A fixed cell according to any of claims 31 to 33 wherein the CD4 receptor is a
- 15 CD4 surrogate molecule.
35. A fixed cell according to claim 34 wherein the CD4 surrogate molecule is M33 mini-protein.
- 20 36. A fixed cell according to any one of claims 31 to 35 wherein the HIV envelope protein is HIV-1 envelope protein.
37. A fixed cell according to any one of claims 31 to 36 wherein the HIV envelope protein is primary CCR5-dependent HIV envelope protein.
- 25 38. A fixed cell according to any one of claims 31 to 37 wherein the HIV envelope protein is gp160.
39. A fixed cell according to any one of claims 31 to 38 wherein the fixed cell is
- 30 derived from a T-cell.
40. A fixed cell according to any one of claims 31 to 39 wherein the fixed cell is

fixed with glutaraldehyde.

41. A fixed cell according to any one of claims 31 to 40 for use in medicine.

5 42. A method of treating or preventing HIV infection which method comprises administering to a subject a fixed cell as defined in any one of claims 31 to 40.

43. A method of treating or preventing a disease or condition of, or related to, the immune system which method comprises administering to a fixed cell as defined in
10 any one of claims 31 to 40.

44. A method according to claim 43 wherein the disease is a T-cell mediated disease.

15 45. A method according to claim 44 wherein the disease is a CD4+ T cell mediated disease.

46. A method according to claim 43 wherein the condition is inflammation.

20 47. A vaccine comprising the fixed cell as defined in any one of claims 31 to 40.

48. Use of a fixed cell as defined in any one of claims 31 to 40 for the preparation of a medicament for use in generating anti-HIV monoclonal antibodies.

25 49. An antibody immunospecific for the fixed cell as defined in any one of claims 31 to 40.

50. An antibody according to claim 44 wherein said antibody is immunospecific for CD4-gp120 complex.

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51. An antibody according to claim 49 wherein said antibody has greater immunospecificity for said CD4-gp120 complex than either gp120 or CD4 alone.

52. An antibody according to any of claims 49 to 51 for use in medicine.
53. A method of treating or preventing HIV infection which method comprises
5 administering to a subject an antibody as defined in any of claims 49 to 51
54. A method of treating or preventing a disease or condition of, or related to, the
immune system which method comprises administering to a subject an antibody as
defined in any of claims 49 to 51.
- 10 55. A method according to claim 54 wherein the disease is a T-cell mediated
disease.
56. A method according to claim 55 wherein the disease is a CD4+ T cell mediated
15 disease.
57. A method according to claim 54 wherein the condition is inflammation.
58. A hybridoma cell line having the identifying characteristics of the cell line
20 deposited with the Advanced Biotechnology Center Inter Lab Cell Line Collection
(CBA ICLB) wherein said hybridoma produces DB-81.
59. An antibody molecule produced by the hybridoma of claim 59.
- 25 60. An antibody that specifically binds the same idiotope as the antibody produced
by the hybridoma of claim 59.
61. A method of generating a fixed cell according to the invention comprising
- 30 (i) expressing HIV envelope protein on the surface of living cells;
(ii) complexing the envelope protein of (i) with a CD4 receptor; and
(iii) fixing the CD4 coated cells.

62. A method according to claim 61 wherein said HIV envelope protein is expressed on the surface of the living cell by transducing the cell with a vector encoding the HIV envelope protein.

63. A method according to claim 61 or 62 wherein CD4 receptor is expressed from the living cell.

64. A method according to claim 63 wherein the living cell expresses said HIV envelope protein and said CD4 receptor from a single vector.

65. A pharmaceutical composition comprising a fixed cell according to any one of claims 31 to 40 and a pharmaceutically acceptable diluent or excipient.

66. A pharmaceutical composition comprising a population of fixed cells according to any one of claims 31 to 40, wherein within the population more than one HIV envelope serotype is expressed, and a pharmaceutically acceptable diluent or excipient.